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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 16, 2000, from 8:30 a.m. to 5:30 p.m., and March 17, 2000, from 8 a.m. to 1 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 16, 2000, the committee will discuss: (1) New drug application (NDA) 21-063, Eloxatin® (oxaliplatin), Sanofi Pharmaceuticals, Inc., indicated for the first-line treatment of patients with advanced colorectal cancer in combination with 5-U based chemotherapy; and (2) NDA 20-571/SE1-009, Camptosar® Injection (irinotecan hydrochloride injection), Pharmacia and Upjohn Co., indicated as a component of first-line therapy for patients with metastatic carcinoma of the colon or rectum. On March 17, 2000, the committee will discuss NDA 21-174,

gemtuzumab zogamicin, Wyeth-Ayerst Laboratories, indicated for the treatment of patients with CD33 positive acute myeloid leukemia in relapse.

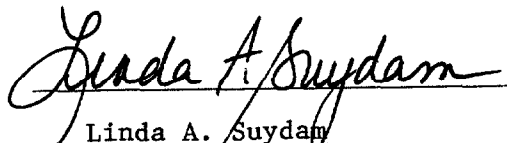
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 8, 2000. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and 1:30 p.m. and 1:45 p.m. on March 16, 2000, and between approximately 8:15 a.m. and 8:45 a.m. on March 17, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 8, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by March 8, 2000, to address issues specific to the submission or topic before the committee.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 1/28/00

January 28, 2000



Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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